

§ 888.3810

chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification.* Class II.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification.* A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

§ 888.4200 Cement dispenser.

(a) *Identification.* A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

(b) *Classification.* Class I. The device is exempt from the premarket notification

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procedures in subpart E of part 807 of this chapter.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994]

§ 888.4210 Cement mixer for clinical use.

(a) *Identification.* A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement (§ 888.3027).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994]

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (§ 888.3027).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988]

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a tube-like device usually made of plastic intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement (§ 888.3027).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994]

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.